

**REMARKS**

The above-identified application has been reviewed in light of the Final Office Action mailed on April 12, 2010. Claims 11-12, 15-20, 28, 31-33, 39-40 and 42-46 are currently pending. It is respectfully submitted that the pending claims are fully supported by the specification, introduce no new matter, and are patentable over the references of record. Reconsideration of the pending claims is earnestly requested.

In the Final Office Action, Claims 11, 12, 15-19, 28, 31-33 and 44-46 were rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,176,127 to Dormia (hereinafter referred to as "Dormia") in view of U.S. Patent No. 6,332,877 to Michels (hereinafter referred to as "Michels"). Applicants respectfully submit that independent claims 11 and 28 are allowable over Dormia in view of Michels.

According to § 2143.03 of the MPEP, "[a]ll words in a claim must be considered in judging the patentability of that claim against the prior art." It is Applicant's position that all the words of the independent claims, as specified above, are not taught or suggested, either expressly or implicitly, by either of the above cited art.

Independent claim 11 recites an orifice introducer device comprising, *inter alia*, a tubular member and a distal portion including a proximal end having an annular groove having "a side of the annular groove constrains the proximal end of the distal portion against radial contraction, wherein, when the distal portion is detached from the distal end of the tubular member, the proximal end of the distal portion contracts from a radially outward position to a radially inward position." (Emphasis added).

Independent claim 28 recites a method for using an orifice introducer device comprising, *inter alia*, the steps of: providing a tubular member having a distal end; and detachably securing a proximal end of a distal portion to the distal end of the tubular member by receiving the distal end of the tubular member in an annular groove at the proximal end of the distal portion such that contact between the distal end of the tubular member and a side of the annular groove constrains the proximal end of the distal portion against radial contraction; the distal portion contracting so as to have a diameter smaller than a diameter of the tubular member.” (Emphasis added).

Independent claim 44 recites an orifice introducer device comprising, *inter alia*, a tubular member and a distal portion including a proximal end having an annular groove having “a side of the annular groove constrains the proximal end of the distal portion against radial contraction, wherein, when the distal portion is detached from the distal end of the tubular member, the proximal end of the distal portion contracts from a radially outward position to a radially inward position.” (Emphasis added).

In an embodiment of the present application, as seen in Figures 3B and 3C, reproduced below, the proximal end 325 of the distal portion 310 is annularly shaped so as to be attachable to the distal end 315 of the tubular member 300. More specifically, as shown below in Figure 3B, the proximal end 325 of the distal portion 310 includes an annular groove 320 that is configured to receive the distal end 315 of the tubular member 300. Figure 3C illustrates a portion of the annular groove 320 that is configured to be frictionally retained between opposing members 320a and 320b the distal end 315 of the tubular member 300. (See Paragraph [0034] – [0035] of the present application).

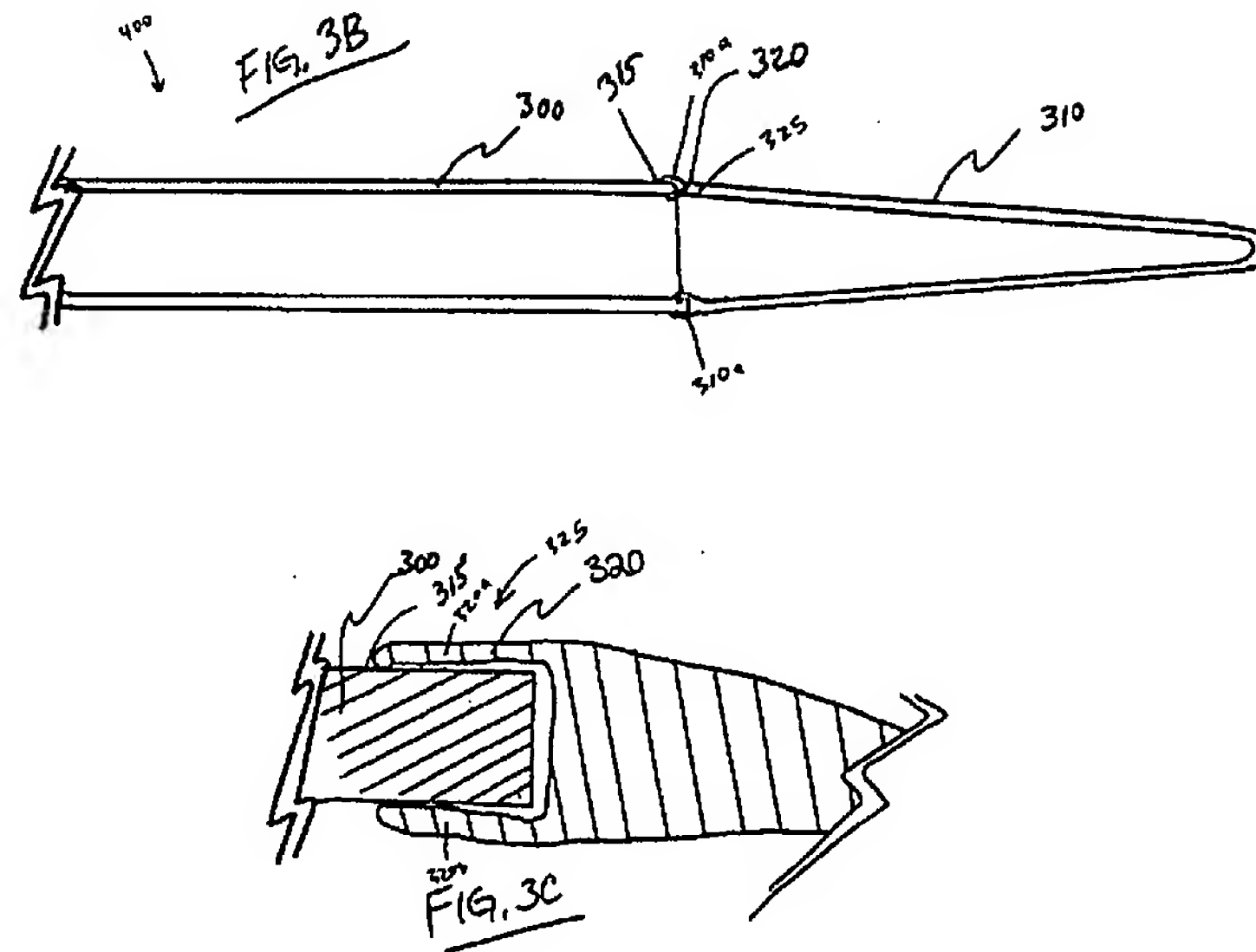
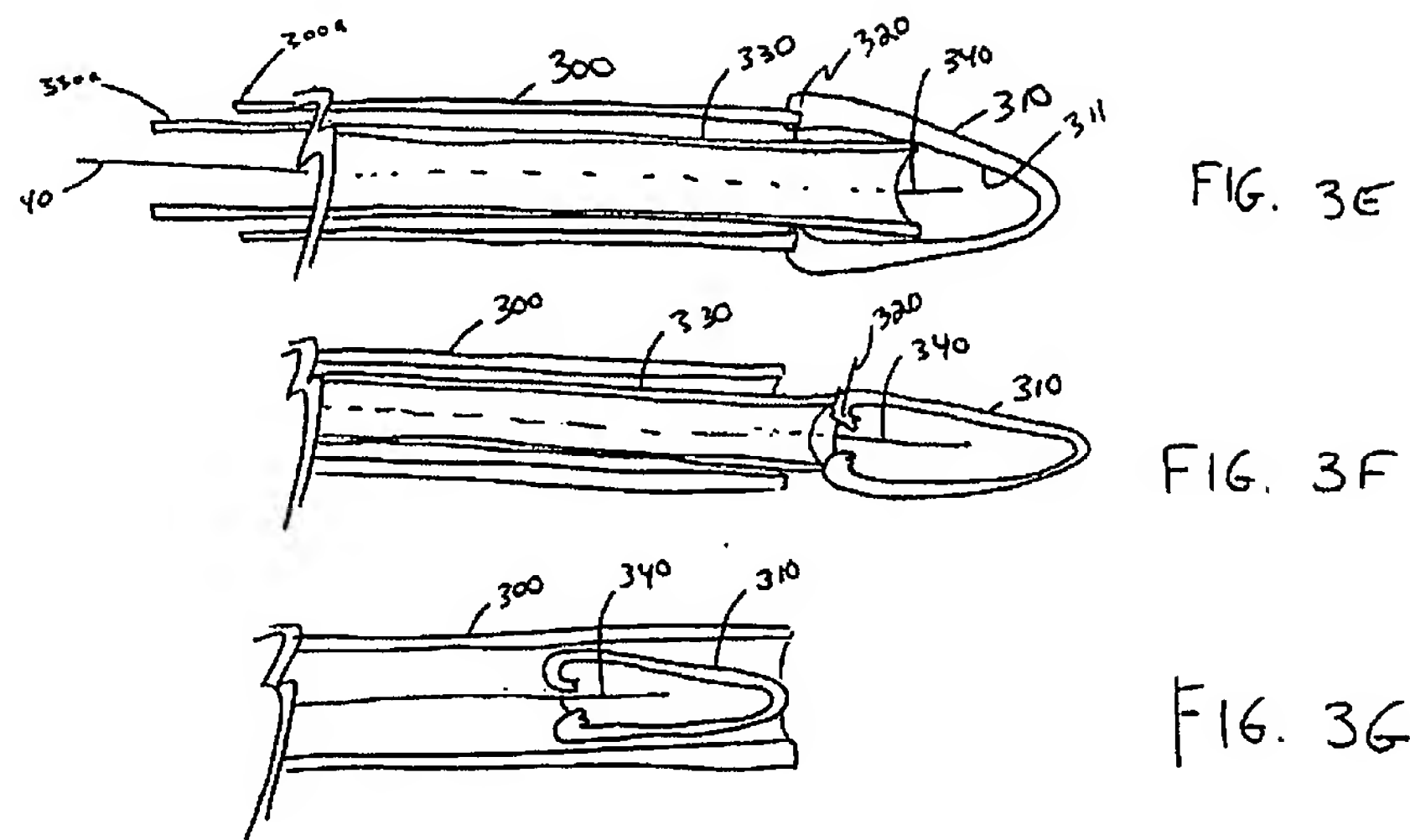
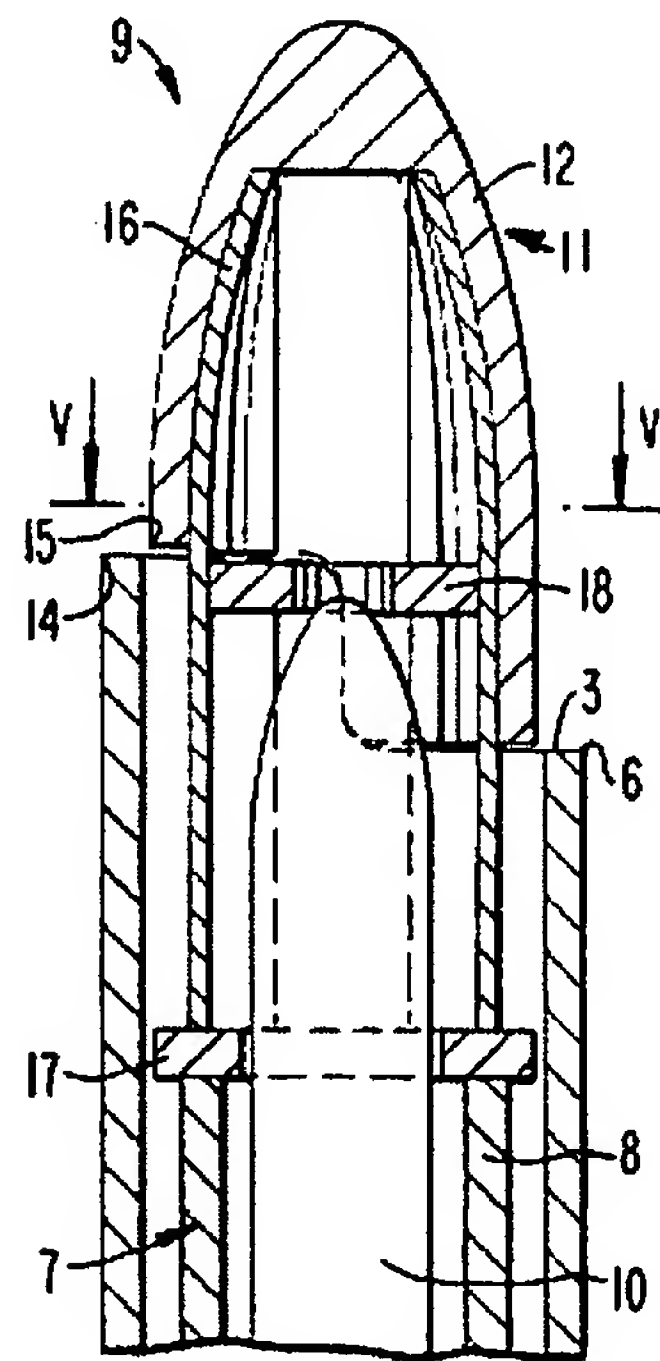


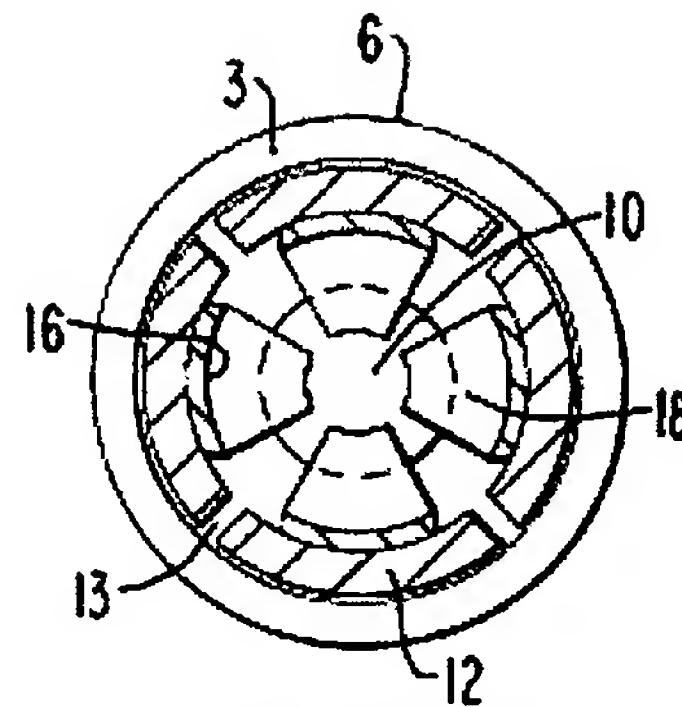
Figure 3E, reproduced below, illustrates the proximal end 325 attached to the distal portion 310 being in the radially outward position. Figures 3F-3G, reproduced below, illustrate the proximal end 325 of the distal portion 310 being in the radially inward position. For example, the annular groove 320 is biased so as to bend inwardly, e.g., to have a reduced diameter, when the distal end 315 of the tubular member 300 is not inserted in the annular groove 320. The proximal end 325 of the distal portion 310 is sufficiently biased such that, when the distal end 315 of the tubular member 300 is not inserted in the annular groove 320, the inwardly-bent proximal end 325 of the distal portion 310 has an outer diameter that is less than an inner diameter of the tubular member 300. (See Paragraph [0035] – [0036] of the present application).



In contrast, Dormia discloses, as shown in Figures 3 and 5, reproduced below, a spreadable head 9, a rod-shaped slide 10, and a jacket 1 of an endoscope. The spreadable head 9 is divided into four head segments 12, which are separated from each other by longitudinal slots 13. When the rod-shaped slide 10 is inserted within the spreadable head 9, the segments 12 are spread outwards until the outer circumferential edge 15 covers the underlying edge 6 of the jacket 1 of the endoscope. (See Dormia at col. 4, lines 3-32). Thus, Dormia does not disclose that a side of the annular groove constrains the proximal end of the distal portion against radial contraction, as substantially called for in claims 11, 26 and 44. Further, Dormia does not disclose that when the distal portion is detached, the proximal end of the distal portion contracts from a radially outward position to a radially inward position, as substantially recited in claims 11, 26 and 44.

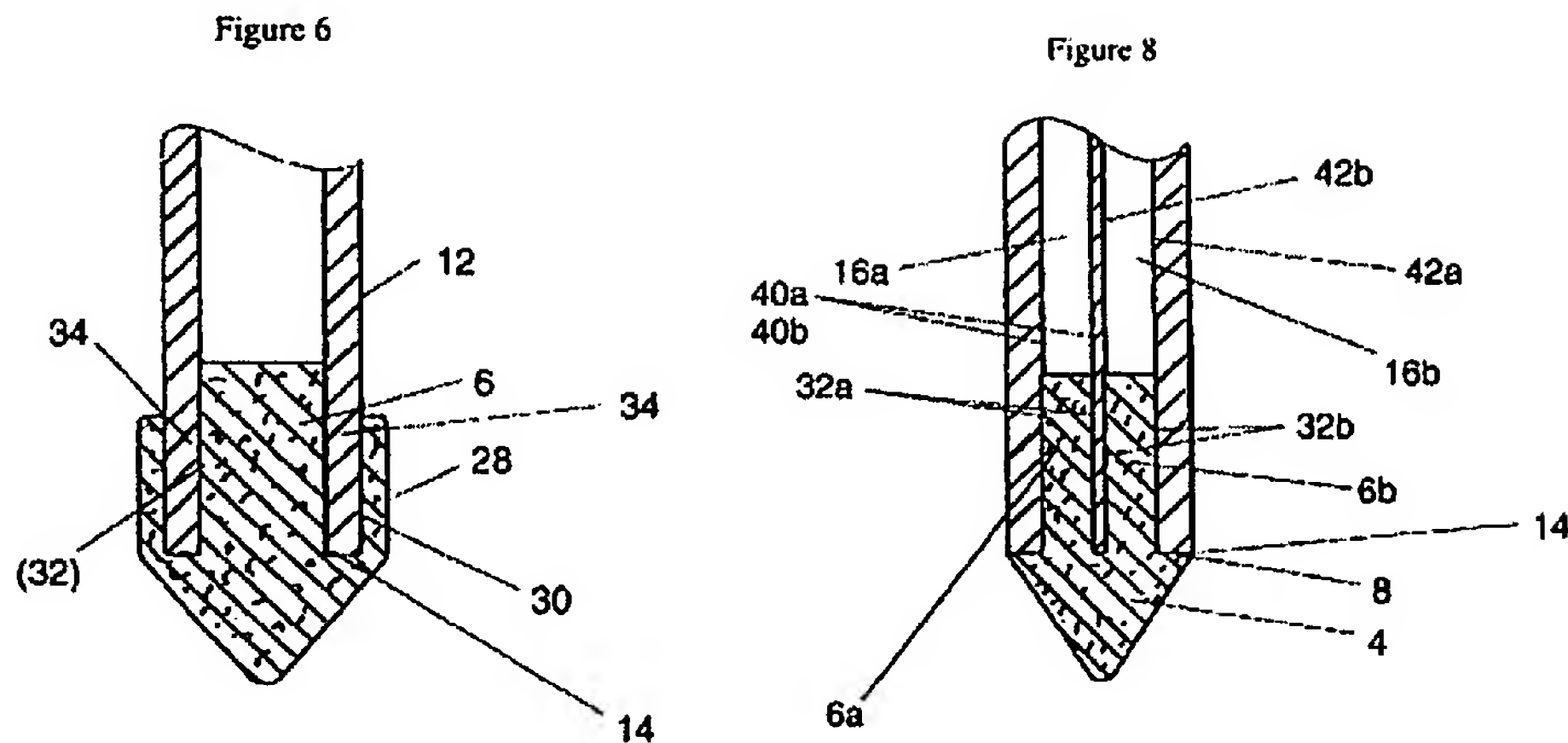


**FIG. 3**



**FIG. 5**

Michels discloses an ostomy tube including a body portion 6, as shown in Figure 6, reproduced below, that is designed to fit within the lumen of the tube 12, while the outer cylindrical skirt 28 fits over and surrounds the periphery of the tube 12. (See Michels at col. 6, lines 16-21). Michels further discloses body portions 6a and 6b, as shown in Figure 8, reproduced below, that are designed to fit within the lumen of the tube 14, while the while the base 8 of the cap and head portion 4 is flush with the tip of the tube 14. (See Michels at col. 6, lines 33-37). Applicants submit that the constructions of the body portions 6, 6a and 6b of Michels is such that any proximal end of the distal portion cannot contract from a radially outward position to a radially inward position, as substantially called for in claims 11, 28 and 44.



Additionally, on pages 2 and 3 of the Final Office Action, the Examiner states the following:

Dormia does not disclose that the distal portion has an annular groove that receives the distal end of the tubular member such that contact between the distal end of the tubular member and a side of the annular groove constrains the proximal end of the distal portion against radial contraction. However, Michels discloses many different configurations for the distal portion (see Figs 5-8, such as one configuration where the distal tip just contacts the distal end of the tube (Fig. 8) which is equivalent to Dormia's cap (Fig. 8)...**Doing so will provide a more secure attachment and prevent slippage that could be caused by the user during delivery. The distal skirt will constrain the proximal end of the distal portion against radial contraction.**

(Emphasis added).

Further, on page 6 of the Final Office Action, the Examiner states the following:

Applicant is reminded that the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggest in any one or all of the reference. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the

art...[i]n this case it is the outer skirt of the tip (for example 28) that is being incorporated into the Dormia [sic] tip to form a groove. The groove and outer skirt will provide a secure attachment and prevent any slippage that could be caused by the user during delivery.

In view of the forgoing, Applicants respectfully submit that Dormia and Michels, either alone or in any proper combination with each other, do not teach or suggest that “a side of the annular groove constrains the proximal end of the distal portion against radial contraction” and “when the distal portion is detached, the proximal end of the distal portion contracts from a radially outward position to a radially inward position,” as recited in claims 11, 28 and 44. Dormia’s primary purpose is to expand and contract the spreadable head 9.

Moreover, according to § 2143.01 of the MPEP, “[i]f the proposed modification or combination of the prior art would change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims *prima facie* obvious. *In re Ratti*, 270 F.2d 810, 123 USPQ 349 (CCPA 1959).”

If the outer skirt 28 of Michels is incorporated into the spreadable head 9 of Dormia, as the Examiner suggests that one of ordinary skill would allegedly do, when the rod-shaped slide 10 of Dormia is inserted within the spreadable head 9, the segments 12 would not be able spread outwards until the outer circumferential edge 15 covers the underlying edge 6 of the jacket 1 of the endoscope, as disclosed in the specification of Dormia. Thus, since the proposed modification or combination of Michels would change



the principle of operation of the Dormia, Applicants submit that the teachings of Dormia and Michels are not sufficient to render the claims *prima facie* obvious.

Since claims 11, 12, 15-19 and 44-46 depend, directly or indirectly, from claim 11 and contain all the features of claim 11, and claims 31-33 depend, directly or indirectly, from claim 28, Applicants respectfully submit that for at least the reasons stated above for claim 11 and 28, claims 12, 15-19, 31-33 and 44-46 are also allowable under 35 U.S.C. § 103(a) over Dormia in view of Michels.

In the Final Office Action, claims 20 and 39-43 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Dormia in view of Michels, as applied to claim 11, and further in view of U.S. Patent No. 6,042,538 to Puskas (hereinafter referred to as “Puskas”). Applicants respectfully submit that independent claim 39 is allowable over Dormia in view of Michels, as applied to claim 11, and further in view of Puskas.

Independent claim 39 recites a device comprising, *inter alia*, a tubular member and a distal portion including a proximal end having an annular groove having “a side of the annular groove constrains the proximal end of the distal portion against radial contraction, wherein, when the distal portion is detached from the distal end of the tubular member, the proximal end of the distal portion contracts from a radially outward position to a radially inward position.” (Emphasis added).

As discussed above, with respect to independent claims 11, 28 and 44, Applicants respectfully submit that Dormia and Michels, either alone or in any proper combination with each other, do not teach or suggest that “a side of the annular groove constrains the



proximal end of the distal portion against radial contraction” and “when the distal portion is detached, the proximal end of the distal portion contracts from a radially outward position to a radially inward position,” as substantially recited in claim 39. Puskas does not cure the deficiencies of Dormia and Michels, nor is Puskas cited in the Final Office Action as curing the above-noted deficiencies of Dormia and Michels. Rather, Puskas is merely cited as disclosing inserting instruments into an endoscope that include retractors, staplers, suction devices, and electric devices. Since Puskas does not cure the deficiencies of Dormia and Michels, with respect to claim 39, Applicant submits that the subject matter of claim 39 is patentable over Dormia and Michels, as applied to claim 11, and further in view of Puskas and that claim 39 is in condition for allowance.

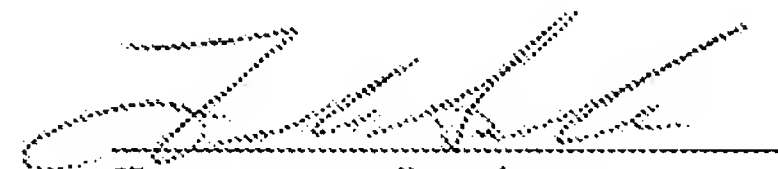
Since claims 40 and 42-43 depend directly from claim 39 and contain all the features of claim 39, Applicants submit that claims 40 and 42-43 are also allowable under 35 U.S.C. § 103(a) over Dormia in view of Michels, as applied to claim 11, and further in view of Puskas. Furthermore, since claim 20 directly depends from independent claim 11 and contains all of the limitations thereof, Applicants respectfully submit that the subject matter of claim 20 is patentable for at least the reasons that independent claim 11 is patentable.

In view of the foregoing amendments and remarks, Applicants respectfully submit that claims 11, 12, 15-20, 28, 31-33, 39, 40 and 42-46 are in condition for allowance.

Should the Examiner desire a telephonic interview to resolve any outstanding matters, the Examiner is sincerely invited to contact the undersigned at the number indicated below.

An early and favorable response on the merits is earnestly solicited.

Respectfully submitted,



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